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The FDA's Use of Adverse Publicity

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Of all the regulatory tools available to the FDA in fulfilling its duties, one of the most contentious and problematic is its use of adverse publicity. Whether it is because of its quasi-statutory status, the questionable legality of its often unregulated use, or its great potential for harm to those it is directed at, there are many who object to the use of adverse publicity by the FDA. However, one cannot deny its significant effectiveness as a regulatory tool and its often

necessary and justified use in protecting the public health and safety. The purpose of this paper, then, is to explore the FDA's use of adverse publicity and the issues and conflicts that arise as a result.

I. What is Publicity and How is it Used?

First and foremost, it should be made clear what is meant by publicity. The term

publicity is reserved for statements which invite public attention and which may adversely affect individuals identified therein.' This means that it is limited to *affirmative* issuance of publicity

'Administrative Conference of the United States, 1 C.F.R. §305.73-1, Adverse Agency Publicity (1973).

by the FDA. Disclosing facts or records requested by an individual under federal information disclosure statutes such as the Freedom of Information Act is not included. This also excludes routine agency lists of enforcement actions or decisions that the FDA is mandated to publish,² such as the FDA's weekly recall lists.³

The FDA uses a variety of channels for publicity. It issues press releases and public announcements and warnings, and utilizes formal press conferences, briefings, interviews, speeches, individual letters, and other forums.⁴ Published reports and announcements also appear in the *FDA Consumer*, the *FDA Enforcement Report*, the *Federal Register* and other private journals.⁵

Although the FDA may issue press releases and announcements for various reasons in various situations, its use of adverse publicity is most often in connection with product recalls. Firstly, publicity from the FDA, and even the manufacturer, may be necessary to recover and warn the public against hazardous products subject to recall. Publicity is the only effective means of removing and notifying the public of products that have gotten past the recall, have already been distributed by the manufacturer, are in the market, and perhaps already in the hands of the consumer. A dramatic public warning by the FDA is the only way to limit or halt

221 U.S.C. §375

³One commentator has also noted, though, that issuance of recall lists is problematic for its own reasons. For example, the list of products is often out-of-date, appearing so long after the event that it gives the impression that there is a second separate problem with the product. Also, they fail to distinguish between actual recalls and stock checks or field corrections. See Richard S. Morey, Publicity as a Regulatory Tool, 30 *Food Drug Cosm. L. J* 469, 470 (1975).

⁴U. Hui, *United States Food Laws, Regulations and Standards*, 478-79 (1979).

⁵ *Id*

consumption before it is too late. This is assuming, of course, that the manufacturer has agreed to the FDA's recall *request*, as the FDA currently does not have the statutory power to *order* recalls. Secondly, if a manufacturer does *not* agree to the FDA's recall request, the FDA may decide to use the threat of adverse publicity to persuade the company to comply and recall its product, in addition to its supplemental use as a general warning to the public.

II. Statutory Authority for the Use of Publicity

The FDA is one of the few federal agencies in government which is specifically required and authorized by law to use publicity. This is provided by Section 705 of the Food, Drug and Cosmetic Act (FD&C) of 1938,⁶ ⁷which reads:

Sec. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, *imminent danger to health, or gross deception of the consumer*. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department. [emphasis added]

621 U.S.C. §375.

⁷In addition to Section 705 of the FD&C Act, the FDA, under delegation of authority of the Secretary of Health, Education and Welfare, may issue publicity under the Federal Hazardous Substances Act (15 U.S.C. § 1272) concerning products which constitute a danger to health. Section 13 of the Hazardous Substances Act is nearly identical to Section 705 of the FD&C Act. In addition, the Office of Product Safety, the division of the FDA which is charged with the enforcement of the Hazardous Substances Act, may publish in the *Federal Register*, without a prior hearing, notice that particular products constitute an imminent danger to public health and that such products are banned hazardous substances (15 U.S.C. §1261(q)(2)).

The first paragraph of Section 705 is rather clear and straightforward in its purpose. It directs and requires the Secretary to publish reports summarizing judgments, decrees, and orders in each case brought under the Act. These are the familiar Notices of Judgment.

It is under Section 705(b), however, that controversy necessarily arises. Besides authorizing the Secretary to report its investigations, the paragraph clearly allows the FDA to direct publicity at specific foods, drugs, cosmetics, and medical devices, *but only* in situations which, in the opinion of the Secretary, involve imminent danger to health or gross deception of the consumer. The question is and remains whether the FDA has followed these seemingly high standards, or has overstepped its bounds and employed publicity beyond the certain situations in which there is a need for such a powerful sanctioning tool.

Publicity, some argue, was never intended to be used routinely or lightly by the Agency for relatively trivial problems, situations where there is no justification for affirmative publicity in terms of the public's need to know, no imminent danger or gross deception. One commentator, for example, points out an incident of the unjustified use of publicity by the FDA, involving a Class III recall of 15,000 candy bars for rancidity.⁸ A Class III recall is defined as a routine situation in which the consequences to life (if any) are remote or non-existent. The well-known manufacturer agreed to recall its product because the bars had developed a slight off-taste that did not pose a health hazard. Nevertheless, the FDA still decided to publicize the incident, which was even reported in the *Wall Street Journal*, undoubtedly causing a not insignificant amount of injury to the manufacturer's reputation and financial worth.

⁸See Richard S. Morey, Publicity as a Regulatory Tool, 30 *Food Drug Cosm. L. & 469*, 470 (1975).

Ultimately, it comes down to an insoluble issue of judgment, prediction, and degrees. Because of the inherent uncertainty involved in dealing with food, drugs, cosmetics, medical devices, etc., there will always be disagreement as to how imminent a danger really is, or whether or not a practice is a gross deception on the part of the manufacturer. This may be why the statute leaves the determination to the FDA and the opinion of the Secretary.

III. Judicial Interpretation of the Authority for. Extent of. and Limits on the F Publicity

One of the first cases to address the FDA's use of publicity was *Hoxsey Cancer Clinic, Inc. v. Folsom*,⁹ in which plaintiffs attempted to enjoin the FDA's dissemination of posters that warned the public that the so-called Hoxsey cancer treatment was worthless.¹⁰ The court essentially upheld the FDA's use of publicity as constitutional, against claims that it was a denial of due process, even though it does not provide for any notice or hearing before publicity is issued. More importantly, the court suggests that the FDA actually has an implied authority to use publicity because of the nature of its regulatory duties. Even in the absence of this statute [Section 705 of the Food, Drug and Cosmetic Act] there would be nothing to prevent the defendants from disseminating information to the public....The defendants [FDA] are performing a public duty when they are urging the use of certain treatments or warning the public against the use of certain treatments. The only purpose of this statute is to place within the express scope of

~155 F. Supp. 376 (D. D.C. 1957).

~ s warning against the Hoxsey cancer treatment was, at the time, the most widely circulated warning ever issued by the FDA. As reported by Wallace F. Janssen (Director of FDA Public-Information Activities), Public Information Under the Food, Drug, and Cosmetic Act — IV, 12 *Food Drug Cosm. L. ii* 566, 576 (1957).

the duties of the Secretary something that was one of his implied functions. Thus, the court affirmed the use of publicity by the FDA as both constitutional and an inherent part of its authority.

The FDA, however, *has* been chastised by the courts for inappropriate use of publicity. For instance, in the case of *United States v. Abbott Laboratories*,¹² the FDA released prejudicial pre-trial publicity in the form of a press release naming Abbot Laboratories and associating fifty blood poisoning deaths with the use of Abbott intravenous solutions, even after Abbot had issued a nationwide recall of its solutions two months earlier. The court accepted without question, that the pretrial publicity in this case was prejudicial and highly inflammatory.¹³ It had even more harsh words for the FDA: Irrespective of the outcome of this case, we join in the district court's condemnation of this conduct and express our strongest disapproval that highly placed legal officers would make a statement of this import with regard to a pending criminal prosecution, and even more so that FDA, which had [already] referred the matter to the Department of Justice, would issue a press release containing such prejudicial material.¹⁴ Nonetheless, even though the court recognized the impropriety of the FDA's publicity, it still refused to dismiss the indictment against Abbott, since voir dire and other procedures were still available to assure a fair trial. Additionally, we must remember that, in this case, the s publicity was ruled inappropriate mainly because it was prejudicial to the pending trial, and not

155 F. Supp. at 378.

12505 F.2d 565 (4th Cir. 1974).

¹³ *Id.* at 570.

¹⁴ *Id.* at 571.

because it was unjustified or unnecessary (though the fact that Abbott's products had already been recalled months earlier, and the matter had already been turned over to the Department of Justice, were undoubtedly factors in the court's decision). Thus, the case does not necessarily shed much light on the limits of the FDA's 'justified use of publicity, though it demonstrates that courts do recognize limits to the FDA's use of publicity.

Another court, however, actually did *explicitly* recognize, for the first time, the limitations placed on the FDA by Section 705(b). The case of *United States v. International Medication Systems, Ltd (IMS)*⁵ initially involved an action by the FDA for preliminary and permanent injunction against IMS, charging a number of violations of the FD&C Act, including failure of the IMS plant to comply with current good manufacturing practice (GMP) requirements. During a period of evidentiary hearings, FDA representatives met with IMS, requested that IMS recall its products, and indicated that if the request were refused, the FDA would inform the nation's hospitals that a public health hazard was presented by IMS products because of the alleged GMP violations. IMS, though, refused this demand because it felt it was unjustified and involved essentially the same issues already before the court in Los Angeles in the pending case. Consequently, on June 9, 1973, the FDA sent a letter to the nation's approximately 7,000 hospitals, stating that the sterility of IMS units was compromised and claiming that the products presented a potential hazard to public health. Ultimately, the court not only denied the FDA's motions for injunction but, more importantly, found that the FDA had violated Section 705(b) of the FD&C Act and overstepped its publicity authority in sending its letter to the nation's hospitals. Additionally, the court even ordered that the FDA issue corrective publicity in the

⁵Civ. No. 73-626-WPG (CD Cal. 1973), *affd*, No. 73-3260 (9th Cir. 1974).

form of a second letter to the same hospitals, reporting the court's ruling and the specific finding by the court that IMS was not shown to be guilty of violation of good manufacturing practices to the extent that its products represent a potential hazard to the public health.¹⁶ 17 Thus, the *International Medication* case is significant as the first instance in which courts have recognized that there are unjustified or inappropriate uses of publicity by the FDA that violate the standards set in Section 705(b). Just as significant is its holding that a manufacturer or company may be entitled to relief in the form of corrective publicity issued by the FDA to remedy the harm done by earlier, unjustified, adverse publicity.

Furthermore, the courts have ruled that they *do* have the power to restrict and enjoin the FDA from issuing news releases and other public statements, particularly when it is pre-trial publicity in connection with a regulatory action. As the court in *US. v. An Article of Device.... Diapulse Manufacturing Corporation of America*¹⁸ stated, a United States Court undoubtedly has inherent power — indeed, is under a plain duty — to take whatever action may be necessary and appropriate to assure a fair trial, regardless of how the proceedings are labeled:

criminal, civil, admiralty or otherwise. The assurance of a fair trial includes safeguarding against prejudicial pre-trial publicity, regardless of the type of action.¹⁹ However, despite this

¹⁶Cited in Morey, 30 *Food Drug Cosm. L.* I at 476.

¹⁷Following this ruling by the court, however, the FDA and IMS reached an agreement under which IMS withdrew its request for relief under Section 705. Therefore, the court's final written order only denied the FDA's motions for injunction and did not contain the corrective publicity relief/order contemplated in the court's oral statement on June 15, 1973.

18262 F. Supp. 728 (D. Conn. 1967).

¹⁹*Id* at 730

affirmation of the courts' inherent power over particular FDA publicity, the *Diapulse* court ultimately did not use this power in its particular case. Instead, it deferred to the FDA's 'justified use of publicity as part of performing its duties. As the court again stated, the instant case is a striking example....of a situation where it would be most inappropriate for the federal judiciary — under the guise of exercising its undoubted power to safeguard parties to a pending proceeding against prejudicial pre-trial publicity — to attempt to muzzle an agency of the executive branch of the government in performing a duty expressly entrusted to it by Congress in 21 U.S.C. §375(b), including the dissemination of information and reporting the results of investigation. ²⁰ The court found that the statements made by the FDA concerning the Diapulse case were factual statements of claims in no way prejudicial to claimant, and reflect a commendable performance by the FDA of a public duty imposed by Congress in disseminating information... [and] warning 'the public against the use of certain treatments.' [citation omitted]²² In addition, the court found that Diapulse had failed to establish any irreparable injury or any threat thereof.²³ Therefore, although it appears that courts have the power to

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²¹The statements made by the FDA consisted of two pages in the Mar. 1966 Report On Enforcement And Compliance that were devoted to the Diapulse case, containing a reasonably factual summary of the claims of the parties (262 F.Supp. at 729); and two sentences in a speech by the Commissioner of Food and Drugs, Dr. James L. Goddard, to the Congress of Medical Quackery on Oct. 7, 1966: You probably know of the 'Diapulse' case. This device, seized in Atlanta, Georgia, used electrical impulses to supposedly treat arthritis, hypertension, sinusitis, middle ear infections, TB, syphilis, toxemia, asthma, hepatitis, diabetes, gangrene, pneumonia, and other conditions.~~

²²262 F.Supp. at 730.

²³*Id*

enjoin certain publicity by the FDA, they may be hesitant to do so when the agency is ostensibly doing its public duty and the affected party lacks any hard evidence of irreparable harm or injury.

IV. FDA Policy Toward the Use of Publicity

Ultimately, the FDA is still strongly devoted to, and values above all, the safety and health of the public. The regulated industry must realize that the FDA will rely on any and all of its varied enforcement tools in protecting the public health,²⁴ including, of course, publicity. In defense of its actions during the 1959 cranberry scare,²⁵ in which millions of dollars worth of cranberries were unsold because of erroneous FDA publicity, the Secretary of Health, Education, and Welfare explained that a responsible government....cannot fail to place at the top of its list of priorities the health of all of the people, even though by doing so it may be or may appear to be acting against the economic interests of a segment of our society.²⁶ In addition, the FDA and certain officers have held the view that the Food, Drug, and Cosmetic Act is a "constitution" as opposed to a grant of power which must be narrowly and strictly construed. Thus, their position may be that the agency has the authority to do anything that Congress has not

²⁴Marie A. Urban, The FDA's Policy on Seizures, Injunctions, Civil Fines, and Recalls,

47 *Food & Drug L.Ji* 411, 411(1992). Marie A. Urban is Director, Division of Compliance Management and Operations, Office of Enforcement/Regulatory Affairs, Food and Drug Administration.

²⁵Discussed more fully in the later section on the effects of FDA publicity, *infra*.

²⁶Testimony of Arthur Flemming, *Hearings before the Subcommittee on Departments of Labor and Health, Education and Welfare and Related Agencies of the House Committee on Appropriations*, 86th Cong., 2d Sess. 165-190, 168-171 (1960).

prohibited it from doing in advance, including the virtually unregulated use of publicity. It appears, then, that the policy of the FDA is that it *will* use any and all of its regulatory tools, including publicity, in its mission to protect the public, despite possible adverse consequences to those affected.

Nevertheless, the FDA, in an official announcement describing its publicity policy and outlining proposed publicity regulations²⁷ recognized and concurred with many Administrative Conference recommendations that actually put limits on the agency's use of publicity.²⁸ For example, it agreed that personally disparaging or gratuitously critical remarks, not required in reporting the facts of a situation, should be and will be avoided, and the FDA recognized that advance notice of FDA's plans to seek publicity that may be adverse is appropriate....to enable affected persons to make a timely response of their own to the press. In addition, it concurred with the recommendation that would require a retraction or correction of erroneous or misleading adverse agency publicity if an affected person requested it. Of course, the FDA also made sure to restate its position that it will continue to seek publicity, when appropriate, even if there is the possibility that the information may be ignored, misinterpreted, oversimplified, overstated, or misunderstood by the media or by the public. Still, it is significant that the FDA actually agreed to recommendations and proposed regulations that limited its own use of publicity.

Unfortunately, despite the s apparent agreement with many of the Administrative

2742 FR 12436 (Mar. 4, 1977).

²⁸The U.S. Administrative Conference, in response to several ill-advised publicity incidents, adopted recommendations respecting the use of publicity by regulatory agencies. See Recommendation 73-1: Adverse Agency Publicity, 38 FR 16839 (June 27, 1973). The Department of Health, Education, and Welfare responded to the Conference's recommendations by adopting regulations codified at 45 C.F.R. Part 17.

Conference's recommendations to improve publicity and its willingness to propose new regulations²⁹ based on these recommendations, the proposed regulations were never finalized. The FDA officially withdrew these proposed rules specifying FDA publicity policy on December 30, 1991.³⁰ As the FDA explained, these proposed rules on publicity policy, as part of a larger group of pre-1986 proposed rules, no longer reflect the agency's regulatory objectives or priorities.³¹ This action was partly in response to criticism that the agency's backlog of pending proposals dilutes the agency's ability to concentrate its attention on higher priority regulations mandated by statute or necessary to protect public health.³² Apparently, then, publicity policy and a revision in the FDA's publicity practices and regulations is no longer of high priority to the FDA. In essence, these proposed rules have become outdated, perhaps necessarily so, due to the increasing scope of duties relegated to the FDA and its concurrently decreasing abilities and resources. As the FDA admits, because of the agency's limited resources and changing priorities, FDA has been unable to consider, in a timely manner, the issues raised by....these proposals and either complete the rulemaking or withdraw the proposals. In many cases, it is unlikely that the agency will have an opportunity to consider these issues in the foreseeable future...the agency believes that the public interest is best served by withdrawing

2942 FR 12436 (March 4, 1977).

3056 FR 67440 (December 30, 1991).

³¹ *Id.* at 67440.

³² *Id.*

these pre-1986 proposed rules.³³ Finally, the FDA offers a further, and ironic, justification for its withdrawal of these proposals. This action would eliminate the uncertainty that may be

presented by the fact that the agency has not issued final rules based on these proposals. This uncertainty may inhibit agency or private sector action to resolve issues by means other than

those set out in the agency's proposed rule. The agency also believes that public confidence in the agency's processes is undermined when the agency initiates, but does not complete, a

rulemaking proposal and fails to give public notice that it does not intend to issue a final rule.³⁴ Of course, this uncertainty and lack of public confidence was created by the agency itself by not following through with its own proposals in the first place. Furthermore, in the specific case of FDA use of publicity, the withdrawal of proposed regulations/policy, instead of eliminating

uncertainty, may simply revert the situation back to the pre-proposal state of uncertainty, where the FDA's policy on publicity was even more unclear and without guidelines.

In fact, the withdrawal of the proposed rules on agency publicity is, practically speaking, advantageous to the FDA. The uncertainty and lack of binding regulations on their use of

publicity provides the agency with the flexibility and discretion that they prefer and need. The concept of flexibility is important to industry and to consumers because the FDA must be able to deal with circumstances individually if it is to carry out its basic mission of consumer

protection.³⁵ Whether or not this was a significant factor in the FDA's decision to withdraw the

~56 FR 42668, 42668 (August 28, 1991).

³⁴ *Id.*

³⁵ Wayne L. Pines (Deputy Asst. Commissioner for Public Affairs of the FDA), Regulatory Letters, Publicity and Recalls, 31 *Food Drug Cosm. L. J.* 352, 359 (1976).

proposed regulations from consideration, or whether their true concerns lie with backlog, limited resources, and higher priority problems, is unclear. Whatever the case, the FDA currently has no *specific* agency policy toward its use of publicity, has withdrawn its proposed regulations, and has no immediate plans for proposing or adopting new regulations.

V. **Detrimental Effects of FDA Publicity**

Given the quasi-statutory and often questionable legal status of the FDA's use of publicity, the relative rarity of courts imposing effective limitations on its use, and the lack of solid, self-imposed agency restrictions or even guiding policy, the agency's almost discretionary use of publicity has a considerable potential for harmful effects.

Publicity, in general, is almost inherently damning, especially to one's reputation, as it usually comes without any notice and without adequate time for response or rebuttal. As the Supreme Court recognized early on, the injuries which are done to character and reputation seldom can be cured, and the most innocent man may in a moment be deprived of his good name, upon which, perhaps, he depends for all the prosperity, and all the happiness of life....Nor can it be fairly said, that the same opportunity is given to vindicate, which has been employed to defame him, for many will read the charge who may never see the answer.. •³⁶ The very characteristics that recommend the use of publicity to the FDA — efficient distribution, saving on agency labor, speed — assure that companies will not be able to stop the publicity once it has left the agency. Once the word is out, the harm has been done. Even if the company is successful in defending against false allegations, it is too little, too late. Exoneration rarely

³⁶ *Respublica v. Oswald*, 1 US (1 Dall) 318 (1788).

commands the same public attention as a charge of wrongdoing.³⁷ Of course, the temporary and perhaps permanent destruction of the consumer market for a particular product, induced by adverse FDA publicity, goes without saying.

Moreover, besides the direct injury and harm to the manufacturer's reputation and product market from FDA publicity, the publicity itself may lead to other, indirect, and perhaps more damaging results. Consider, for example, the effect that constant but trivial and unjustified FDA-issued publicity has on the consumer. He or she can become desensitized and jaded by these minor announcements and not be prepared to act in the case of a real health or safety emergency. Moreover, when rash and imprudent announcements (or denouncements) by the FDA are later discovered to be erroneous, this hurts the agency's credibility with the consumer and, again, the consumer may not fully trust, appreciate, or heed a future FDA warning in a truly critical situation.

Furthermore, adverse FDA press releases on a particular product, because of their official source, may key the media into another topic for consumer scare stories and serve as fodder for sensationalism. This added publicity/sensationalism can dramatically increase litigation and cripple companies. Take the Dalkon Shield and asbestos as examples. The number of claims against the A.H. Robins Company for alleged harm associated with the Dalkon Shield increased exponentially after the media started reporting the cases. The publicity and increased litigation generated a caseload that was too much for the company, and it ultimately

³⁷*Rushford v. Civiletti*, 485 F. Supp. 477, 479 (D. D.C. 1980). See also *GTE Sylvania v. CPSC, Inc.*, 447 US 102 (1980).

filed for bankruptcy.³⁸ Also, the fantastic number of asbestos cases now before federal and state courts — over 60,000 in state courts and 26,000 before one federal judge in Philadelphia — is directly related to secondary publicity by the media.³⁹

There are other secondary effects as well. The FDA's publicity does not necessarily affect only the single manufacturer or product that it is directed at, but will adversely impact the manufacturer's or product's industry as a whole. As a result, companies innocent of any wrongdoing may suffer serious economic loss because the FDA's adverse publicity cannot be focused only on the wrongdoers.

Additionally, publicity will affect a publicly-traded company's financial status when it ultimately hits Wall Street. It will also have an effect on a company's internal operations as employees learn about the FDA's allegations and statements and react accordingly. Large customers such as drug wholesalers and food chains may start rejecting the product in anticipation of expected consumer reaction against it. Finally, with drug or medical companies, the effect on physicians and pharmacists must be considered. Obviously, these middlemen will have to decide whether or not to prescribe the products in question as well as how to respond to patients' inquiries about them. The fear of malpractice claims may force them to cease using, recommending, or prescribing the product, even if they personally believe in the product's safety and effectiveness. In addition, when competing products are on the market, it is likely that competing manufacturers or sales representatives will exploit the situation and further mention

³⁸See Wayne L. Pines, Communications Strategies in Product Liability Crises, 48 *Food & Drug L.J.* 153, 154 (1993).

³⁹*Id.*

the FDA's adverse publicity to physicians, pharmacists, and other potential customers. Perhaps what is most disturbing about the FDA's use of publicity as a regulatory tool is

not just its potential for harm and companies' helplessness in the face of it, but, because of these aspects, how it may force companies to act and surrender when they are, in fact, innocent of wrongdoing. Damaging publicity is often a greater threat to many agency respondents than any official agency sanction.⁴⁰ As a result, it may coerce potential victims into accepting even the most questionable agency views and demands, which, as a result, are never reviewed by the courts. The *International Medication Systems* case, *supra*, has already given us an example of the somewhat coercive use of publicity by the FDA. According to a leading study, four factors determine the coercive effects of agency publicity: 1) the likelihood that adverse publicity will reach the public, 2) the degree to which the public disapproves of the conduct being condemned, 3) the importance of a good reputation to the one against whom the publicity is directed, and 4) the extent to which adverse public impact will deter others in their conduct, beyond the subject company's activities.⁴¹ By this analysis, FDA publicity may be quite coercive: It is very likely that the FDA's adverse publicity will reach the public, not only because of the many publicity channels available to the FDA, but because the subject matter, potential health risks and dangers (some fatal) in our food, drugs, or medical devices, is inherently of (self)interest to the public and media. Of course, this also means that the public disapproves (to say the least) of the conduct that the FDA is condemning, usually the continued manufacture and marketing of unsafe

⁴⁰Note, Disparaging Publicity by Federal Agencies, 67 *Col. L. R.* 1512, 1514 (1967).

⁴¹Gellhorn, Adverse Publicity by Administrative Agencies, 86 *Harv. L. Rev.* 1380, 1383 (1973).

products. In addition, a good reputation is vital to the success of a manufacturer, or any marketer of products, especially in the case of food, drug, and medical device companies. Finally, adverse publicity from the FDA and its effects on companies do serve as a deterrent example to other companies. Therefore, FDA use of publicity may be seen as extremely, and perhaps inappropriately, coercive.~~

VI. The Cranberry Scare

Perhaps the most (in)famous incident involving FDA publicity, and the clearest example of the potential impact of its unfortunate use, was the cranberry scare of 1959.⁴² Shortly before Thanksgiving of 1959, just as the peak season for cranberries sales in the nation began, the FDA discovered that aminothiazole, a pesticide which in very high doses had been shown to induce cancer in rats, had been sprayed on cranberries grown in Washington and Oregon. Cranberries grown in the rest of the United States were not involved, and it ultimately turned out that less than one percent of the nation's cranberry crop was exposed to any aminothiazole hazard. Also, scientists considered that the likelihood of harm from the contaminated cranberries was, at most, speculative, since only low-level, short-term exposure was involved.⁴³ Nevertheless, on November 9, 1959, Secretary of Health, Education, and Welfare Arthur Flemming held a highly publicized press conference in which he urged the public not to eat the contaminated cranberries. Of course, the effect of this FDA publicity was to decimate the entire

⁴²See Morey, 30 *Food Drug Cosm. L. J.* at 471-72, and Edward L. Smith, The Cranberry Scare and Cabinet Immunity, 16 *Food Drug Cosm. L. J.* 209, 209-210 (1961).

⁴³Morey, 30 *Food Drug Cosm. L. J.* at 472.

national market for cranberries in 1959. The cranberry producers' association reported that retail sales dropped 67 percent from Thanksgiving sales in previous years.⁴⁴ Many innocent and non-contaminated cranberry growers suffered serious economic loss because the adverse publicity could not be focused only on those cranberries and growers that were contaminated. There remained a lingering effect on the market for years afterward, although there was no longer any aminothiazole hazard. The incident generated protests from growers, the *New York Times*,⁴⁵ and even the American Medical Association.⁴⁶ Congress eventually indemnified cranberry growers for their losses in the amount of approximately ten million dollars.⁴⁷

VII. Options and Remedies Against FDA Publicity

Unfortunately, the fact of the matter is that, in the face of significant potential or actual harm, affected companies have few effective options or remedies against FDA publicity.

Firstly, and surprisingly, it may be unwise for the manufacturer or company in question to respond to FDA allegations or statements. In considering whether and how to respond, the affected party must keep in mind the credibility of the person or organization making the allegations or statements, in this case the FDA. Usually, when allegations are made, it makes sense, as a countermeasure, to rebut, deny, or clarify them in the press with a follow-up release or

⁴⁴Statement by Ambrose E. Stevens, executive vice president, National Cranberry Institute, in Washington, D.C., quoted in Associated Press dispatch, December 9, 1959.

⁴⁵*New York Times*, November 14, 1959, p. 20, col. 2.

⁴⁶*American Medical Association Journal*, January 2, 1960, p. 62.

⁴⁷*New York Times*, March 31, 1960, p. 1, col. 8.

announcement of some sort, so that false allegations or statements do not stand unchallenged. Repeated long enough, allegations, false or otherwise, will be believed unless they are rebutted. Moreover, allegations, if not rebutted, will remain in newspaper stories forever, available to future reporters interested in later litigation or anyone interested in researching the product or company in question. However, in the case of FDA publicity, the option of responding to statements or allegations may not be available to manufacturers or companies. That is, considering the status and credibility of the FDA, it may not be wise to confront them in public.⁴⁸ The Food and Drug Administration has great credibility and authority with the media and the public. Therefore, it carries the presumption of objectivity. On the other hand, and unfortunately, no one has less credibility than the company being attacked, as the public presumes they have ulterior motives of self-interest. Arguing with the FDA in public may be futile and can actually further damage a company or product's reputation. Therefore, a public response to FDA publicity by an affected company is a risky option.

An alternative option or remedy may be to seek an order requiring the FDA to issue corrective publicity, as was the case in *United States v. International Medication Systems*⁴⁹ (*supra*). However, one must remember that this, as with many other potential remedies against FDA publicity, is a rare accomplishment. Moreover, corrective publicity from the FDA may be a useless gesture: the damage has already been done, and the correction comes too little, too late. As mentioned previously, exoneration rarely commands the same public attention as a charge of

⁴⁸See Wayne L. Pines, Communications Strategies in Product Liability Crises, 48 *Food & Drug L.J.* 153, 156 (1993).

⁴⁹Civ. No. 73-626-WPG (CD Cal. 1973), *affd*, No. 73-3260 (9th Cir. 1974).

wrongdoing.⁵⁰

Affected companies may also consider an injunction or temporary restraining order to stop the further dissemination of any information or publicity by the FDA. As mentioned earlier, courts *have* asserted the power of injunction against the FDA.⁵¹ However, it seems that they may often be hesitant in using it, since they recognize that the FDA may be doing its public duty in disseminating information and publicity, and do not want to interfere and muzzle an agency of the executive branch.⁵² There are also constitutional concerns involved, including the presumption against prior restraint and the conflict between constitutional/publication liberties and private rights.

Consequently, there are strict requirements or factors that must be met before an injunction will issue, requirements which make it difficult for the affected company to prevail. For instance, the affected company or manufacturer must demonstrate that irreparable harm will result if the injunction is not granted. This can be done through affidavits of marketing personnel,⁵³ but injury may have to be economic, immediate, and devastating, which may be difficult to prove for some companies, especially less well-established ones in less well-established industries. In addition, the impact of the injunction on other interested persons will have to be shown; that is, that other similarly situated manufacturers would not be greatly disadvantaged by the injunction should it be granted, or that persons with a demonstrably

⁵⁰ *Rushford v. Civiletti*, 485 F. Supp. 477, 479 (D. D.C. 1980).

⁵¹ See *US. v....Diapulse*, 262 F. Supp. 728 (D. Conn. 1967), *supra*.

⁵² *Id*

⁵³ See, e.g., *Kaiser Aluminum & Chem. Corp. v. CPSC*, 414 F.Supp. 1047 (D. Del 1976).

legitimate interest in the information will not be deprived of information important to them. Perhaps most importantly, an injunction will not issue if public interest in informing the public of the problem or product is so great that it overrides and overweighs the other factors; for instance, if the public will be exposed to an additional and significant adverse effect during the time the injunction is in effect and the product is still on the market for sale or use. This is the most difficult hurdle to get past, as it is the FDA's mission to protect the public health and safety. Ultimately, one must remember that an injunction is a drastic and hard-to-obtain remedy, especially against a federal agency such as the FDA. As the previous cases have shown, they are rarely granted.

Similarly, post-disclosure remedies for recovery of damages caused by FDA publicity are virtually non-existent. Persons who suffer damages as a result of an administrative act have two possible sources of recovery or compensation: the government official whose act caused the injury, or the government itself.⁵⁴ Under present law, however, both sources are immune.

Officials, including the Secretary, are immune from damages for injuries caused by adverse FDA publicity. In the landmark case of *Spalding v. Vilas*,⁵⁵ the Supreme Court ruled that cabinet officers are not liable for defamation in their official communications....in the discharge of duties imposed upon them by law.⁵⁶ Otherwise, effective administration would be seriously hampered by officers' constant fear of liability. *Spalding* was the basis for a long line of federal

⁵⁴Schwartz, *An Introduction to American Administrative Law*, p. 208 (1958).
161 U.S. 483 (1896).

⁵⁶*Id* at 498.

decisions that extended this immunity to federal officials below the cabinet officer level.⁵⁷ Finally, in *Barr v. Mateo*,⁵⁸ the Supreme Court held that government officials have immunity from any tort liability that results from action taken in the exercise of their official responsibilities.⁵⁹ Thus, as long as an FDA official is acting within the scope of his authority — a requirement which has been construed broadly in favor of officials — he or she is protected by an absolute privilege against suit.⁶⁰

In addition, the government itself is immune from a suit for damages under the Federal Tort Claims Act.⁶¹ For example, if a manufacturer is found innocent of an agency charge or allegation but has suffered irreparable injury because of the adverse publicity, it may not recover damages against the government/FDA. While the Federal Tort Claims Act allows suits for the negligent and wrongful acts of the government, it expressly exempts actions based on claims arising from libel, slander, or misrepresentation. In fact, the immunity provided by the Federal Tort Claims Act covers actions done in executing a statute or regulation, even if it is invalid, or

⁵⁷Cases are collected in Handler and Klein, *Defense of Privilege in Defamation Suits Against Government Executive Officials*, 74 *Harvard Law Review* 44 (1960).

58360 U.S. 564 (1959).

⁵⁹One judge has argued that this provision of immunity may have unwittingly created a privilege so extensive as to be almost unlimited and altogether subversive of the fundamental principle that no man in this country is so high that he is above the law. Concurring opinion of Chief Justice Groner, *Glass v. Ickes*, 117 F.2d 273, (CA of DC, 1940). See also the dissent of Brennan, J. in *Barr v. Mateo*.

⁶⁰Besides, a suit against an FDA official is mostly futile, as an individual official will not be a good source of monetary compensation for one's damages, as opposed to the government itself.

6128 U.S.C. 1346(b) (1964).

for acts within any federal agency's discretionary function or duty....whether or not the discretion involved be abused.⁶² Clearly, then, even questionable or perhaps unjustified use of publicity by the FDA may be covered by the Act, thereby making the FDA/government immune.

However, a potential, though rare, way to defeat governmental immunity is to secure the passing of a private bill through the Congress, one that permits the waiver of sovereign immunity for a particular suit. This was the case in *Mizokami v. United States*,⁶³ where farmers sued for the destruction of their 1962 market for summer spinach by erroneous FDA reports of pesticide contamination. As the injured farmers proved in the Court of Claims, news travels fast in the produce business and....the overall effect of the stoppages and erroneous determination was to depress their business and force price cuts⁶⁴ for the remaining crop. By securing the passage of a private bill, the farmers were able to recover more than \$300,000. Of course, the success of such a method or option would require considerable influence in Congress on behalf of the manufacturer or industry in question.

One case, however, has suggested the intriguing idea that perhaps the FDA (or, more precisely, the government) has a moral obligation to recompense the losses suffered by the manufacturer/producer from erroneous, adverse publicity from the FDA. The court in *California Cannery & Growers Assoc. v. U* **8.65** held that the plaintiff, a manufacturer of products containing cyclamates, *could* recover for losses sustained as a result of consumer response to the FDA's

6228 U.S.C. §2680(a) (1952).

63414 F.2d 1375 (Ct. Cl. 1969).

64I[~] at 1381.

657 Cl. Ct. 69 (United States Claims Court, 1984)

erroneous announcement that cyclamates had been found to have caused cancer when ingested by laboratory animals. Cyclamates had not been found to have caused cancer — only the test substance of cyclamates and saccharin had been found to be a carcinogen. The agency's statements were clearly erroneous and wholly lacking in support.⁶⁶ Of course, sales dropped suddenly and dramatically immediately after the Government's statements.⁶⁷ In its reasoning for holding the Government responsible for the manufacturer's losses, the court *did* recognize that it is in the public interest and to the public's benefit that the Government [FDA] engage in such publicity to keep consumers advised of scientific and medical developments and questions concerning a product's safety.⁶⁸ However, the court still decided in favor of the manufacturer:

The marketers of any product should not, in all justice and fairness, be forced to sustain and absorb the losses incurred as a result of erroneous Government statements, particularly those which are wholly unwarranted and carelessly issued.⁶⁹ In fact, even though the events in this case would not give rise to any *legal* claim if brought against a private party, the court still allowed a recovery against the Government, based on an *equitable* claim, recognizing the moral obligation of the United States.⁷⁰ [emphasis added] That is, Plaintiff should be compensated

⁶⁶ *Id* at 91.

⁶⁷ *Id* at 92.

⁶⁸ *Id*

⁶⁹ *Id*

⁷⁰ *Id*

for these losses as an equitable claim based on the moral obligation of the United States.⁷¹ Thus, the court recognizes that the FDA/Government has a *moral obligation*, and therefore an equitable responsibility, to recompense manufacturers and producers for losses due to adverse and erroneous publicity. Of course, the general applicability of this holding may be somewhat limited by just how erroneous the FDA's publicity activity was in this case, or just how direct a cause they were to the plaintiffs damages. For example, the court found that the FDA's publicity was purely informational and not necessary to the regulatory action of recalling cyclamates from the marketplace some 10 months after the first announcements; that the statements were incorrect and without support *at the time they were being made* and not simply found to be erroneous later on; and that the statements by the FDA were the *direct cause* of the manufacturer's drop in sales.⁷²

Unfortunately, two years later, recovery was denied to the manufacturer/canner.⁷³ A reviewing panel found that, in fact, the s statements were not arbitrary, capricious, or lacking in support,⁷⁴ and that the plaintiff had not shown a connection between the statements and the damage amounts claimed. Consequently, since there was no wrongdoing on the part of government officials and employees the essential ingredient for a recommendation of an

⁷¹ *Id.* at 93.

⁷² *Id.* at 90-93.

⁷³ *California Cannery & Growers Assn. v. United States*, 9 Ct. Cl. 774 (1986).

⁷⁴ *Id.* at 784.

equitable award to plaintiff is lacking,⁷⁵ and the equitable award/recovery was denied. Nevertheless, despite the fact that the manufacturer was ultimately denied recovery on mostly factual grounds, this case does *suggest* that the FDA/Government can be morally and therefore legally responsible for recompensing a manufacturer's losses that were due to adverse and erroneous FDA publicity.

VIII. In Defense of FDA Use of Publicity

Firstly, to be fair, one should recognize that much of the publicity associated with the FDA is not FDA-generated, and that the FDA does not necessarily use publicity freely and indiscriminately, for every little thing that comes along. The FDA actually seeks publicity, for example through press releases, less than fifty times a year.⁷⁶ The remainder of the publicity stories about the FDA and the products it regulates are initiated through other sources, mainly because of the great public interest in the safety of products regulated by the FDA. The character and amount of publicity is largely controlled by the press or other media. Rarely is a news release printed in its original form.

Furthermore, the FDA recognizes and believes that a majority of persons desire to comply with the law and will comply voluntarily when given information as to what is required and what violations appear to exist. Thus, the FDA necessarily relies on voluntary industry self-regulation and compliance (including recalls initiated by the manufacturers themselves), and it is FDA

⁷⁵ *Id* at 785.

⁷⁶ Wayne L. Pines (Deputy Asst. Commissioner for Public Affairs of the Food and Drug Administration), *Regulatory Letters, Publicity and Recalls*, 31 *Food Drug Cosm. L.* 352, 354 (1976).

policy that responsible persons be given notice of violations and afforded an opportunity for correction.⁷⁷ In reality, the use of publicity is mainly reserved for situations in which a company refuses to recall a product after a request by the FDA, often in conjunction with seizure and injunction actions, or when a recall may not be sufficiently comprehensive or effective to protect the public (as discussed earlier). And remember, publicity is really the only effective way to remove from the marketplace those dangerous products that reach the consumer and are beyond tracing through the normal distribution system. Therefore, one should recognize that the FDA's use of publicity is often in reaction to dangerous and even emergency situations created by others, and is not a pre-planned devise.

In fact, it is in the FDA's interest to use publicity judiciously. It is only by a careful use of publicity and attention to statements and allegations made that the FDA avoids locking itself into a position well in advance of adjudicatory findings.⁷⁸ For example, FDA decisions to proceed with prosecution are cleared through several levels of review, each with a negative veto over the decision to exercise prosecutorial discretion in that particular case. Premature or position-locking publicity disrupts the process and contradicts the agency's interest in picking strong cases and pursuing them.⁷⁹ Moreover, ill-advised or rash announcements (or denouncements), like the cranberry scare statements, will only hurt the agency's credibility if and when they are discovered to be erroneous, whether or not the agency was justified in making

⁷⁷ *Id*

⁷⁸ See, e.g., *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583 (DC Cir. 1970).

⁷⁹ See 42 FR 12436 (Mar. 4, 1977), FDA proposed publicity policy.

them. The FDA also know[s] what happened to the boy who cried 'adulterated' too often. He got himself and his message 'adulterated.'⁸⁰ So they recognize, too, that the issuance of too many public warnings would simply lessen the impact of a public warning about a serious health hazard.⁸¹ Additionally, the Secretary *is* a politician, and as a politician he is also sensitive to and cannot ignore the pressures of interest groups and other politicians, who may not prefer drastic, polarized actions. Finally, there is always the presence of the options of last resort, removal by the President⁸² and impeachment,⁸³ to temper the Secretary's use of publicity.

Of course, the FDA *does* have a large range of other enforcement and regulatory tools available, potential alternatives that some may prefer over the FDA's informal and unregulated use of adverse publicity. These include recalls, seizures, and injunctions, traditionally the FDA's primary regulatory and enforcement tools, as well as criminal prosecution, warning letters, license suspension and revocation, and withdrawal of product approvals. However, it is often not effective or practical to use these other forms. For example, while many violations could be prosecuted as criminal matters, it would not be responsible, or perhaps even possible, to do so in every case. Also, a criminal prosecution or fine, for example, provides small consolation to a patient who has suffered injury or even death from an unsafe or ineffective food, drug, or medical device. Because of its comprehensive distribution and the lack of agency labor needed, publicity is simply one of the most effective and efficient regulatory tools that the FDA has.

⁸⁰Pines, 31 *Food Drug Cosm. L. J.* at 354.

⁸¹Id.

⁸²See *Myers v. US.*, 272 U.S. 52 (1926).

⁸³U.S. Constitution, Art. II, Sec.4

The effectiveness and efficiency that the use of publicity provides are not only practical advantages, but, in the case of a resource-strapped agency like the FDA, are necessities. It is well known that the scope of the FDA's duties severely strain its limited resources. The FDA has approximately 3,900 personnel involved in enforcement and surveillance activities.⁸⁴ However, the FDA must regulate: approximately 90,000 domestic establishments engaged in the manufacturing, processing, repacking, relabeling, or wholesale storage of various articles; the quality and integrity of research done by 20,000 clinical investigators of food, drugs, devices, and biologics; and the safety of one and a half million import entries each year.⁸⁵ In addition, during a typical year, the FDA will inspect approximately 20,000 establishments, analyze 29,500 samples, and issue 8,000 notices of inspectional findings. The FDA then issues 1,500 warning letters, monitors 2,000 recalls, and initiates 200 seizures, 20 injunctions, and 40 prosecutions.⁸⁶ Understanding the sheer scope and number of FDA activities, one may better appreciate the benefit from and the vital need for any regulatory tool that is effective and can save on limited resources.

Finally, one must remember that, ultimately, the FDA's mission is to protect the public health and to promote honesty and fair dealing in the marketplace,⁸⁷ and it will do almost anything within its authority, and will even push the envelope of its authority, to do so. Of

⁸⁴As of 1992; See Alan L. Hoeting, The FDA's Enforcement Program, 47 *Food & Drug L.J.* 405, 406 (1992).

⁸⁵*Id.*

⁸⁶*Id.* at 407.

⁸⁷Included in the 1935 U.S. Senate Committee on Commerce report entitled Foods, Drugs, and Cosmetics, S. Rep. No. 361, 74th Cong., 1st Sess. (1935)

course, there are times when the decision is tough, when uncertainty about a danger and the threat to public safety from that potential danger, are nearly balanced. However, the decision always must be made in favor of consumer protection. "88 After all, the innocent consumer should not be made the victim...in order to protect the innocent producer.⁸⁹ Alternatively, one may point out that it is the right of the public to know about the dangers that the FDA is aware of, and it is the duty of the FDA to disclose them. Indeed, the Government has no right to withhold from its citizens information about situations or products which may endanger the public health.⁹⁰ Remember, it is only in hindsight that many incidents involving FDA use of publicity seem unjustified.

IX. Solutions to the Adverse Publicity Dilemma

Although the situation seems insoluble at times, there are several suggested measures that can be taken in response to the adverse publicity problem.

First, we should consider amending the Federal Tort Claims Act to include claims for damages arising from acts of libel, slander, or misrepresentation by federal agencies. One commentator has focused on streamlining and systematizing the government's obligation to

⁸⁸Stated in a FDA press release retracting the Stokely-Van Camp botulism false alarm, cited in Morey, 30 *Food Drug Cosm. L. Ji* at 477.

⁸⁹Testimony of Secretary of Health, Education, and Welfare Arthur Fleming, *Hearings before the House Committee on Interstate and Foreign Commerce*, 86th Cong., 2d Sess., H.R. 7624, 63-69 (1960).

⁹⁰Testimony of Secretary of Health, Education, and Welfare Arthur Fleming, *Hearings before the Subcommittee on Departments of Labor and Health, Education and Welfare and Related Agencies of the House Committee on Appropriations*, 86th Cong., 2d Sess. 165-190, 777 (1960).

pay.⁹¹ Currently, the costs of providing justice and fair compensation to victims of agency mistakes are too high. However, revisions could provide compensation, but leave still leave upon the claimant the burden of showing that publicity was directed at the claimant, was uncorrected, and was either materially erroneous, substantially misleading, or clearly excessive. Issues of causation and damage also remain part of the claimant's burden of proof.⁹² A heavier burden of proof would help deter frivolous claims against the government.

It only makes sense that the government should compensate those innocent companies that are injured by adverse FDA publicity. When the public gets the benefit of a program, the public should pay for the torts that may be expected in carrying out the program.⁹³ Also, this option would not unduly burden the FDA or limit its discretion in using publicity to protect the public. However, even if this type of recovery were allowed, it is unlikely that the affected party could be compensated for its entire loss, a loss which includes intangible assets such as reputation and goodwill.

Another potential solution of note is to amend the Food, Drug & Cosmetic Act to provide the FDA with statutory recall authority. Given the connection between the FDA's use of the recall and its use of publicity to help bolster its recall requests and efforts,⁹⁴ granting the FDA the

⁹¹Gellhorn, *Adverse Publicity by Administrative Agencies*, 86 *Harv. L. Rev.* 1380,

1437-40 (1973).

⁹²*Id*

⁹³Davis, 3 *Administrative Law Sec.* 26.07 (1958).

⁹⁴See Section I on how publicity is used, *supra*.

power to order recalls might change the dynamics of this situation⁹⁵ and reduce the FDA's reliance on publicity, and therefore its adverse effects on manufacturers.

Finally, we should seriously reconsider limitations on the circumstances in which agency publicity would be issued. Of course, this process of agency self-examination and revision began when the FDA set out to publish the agency's publicity policy and proposed publicity regulations in 1977.⁹⁶ However, it was discontinued when the FDA withdrew its proposed regulations some 14 years later, before they were ever finalized.⁹⁷ Therefore, a serious effort should now be made to (re)implement the Administrative Conference's findings and recommendations, and the regulations adopted by the Department of Health, Education, and Welfare.⁹⁸ Specifically, a minimal period of advance notice should be adopted, perhaps 30 days for normal notice and 24 hours minimum notice, such as that provided by the Toxic Substances Control Act.⁹⁹ This would allow any respondent a reasonable opportunity to prepare in advance a response to the publicity about to be released. In addition, all adverse publicity should be factual in content and accurate in description. Disparaging terminology not essential to the content and purpose of the publicity should be avoided.¹⁰⁰ This will help eliminate the possibility of libel, slander, and, to a certain extent, misrepresentation. Finally, among other things, the FDA should issue retractions or

⁹⁵Morey, 30 Food Drug Cosm. L.J. at 471.

⁹⁶See earlier discussion of agency policy and 42 FR 12436 (Mar. 4, 1977).

⁹⁷See 56 FR 67740 (Dec. 30, 1991).

⁹⁸45 C.F.R. §§17.1 et seq.

¹⁰⁰45 C.F.R. § 17.2

corrections in the same manner as the original publicity, if the affected party requests it and shows the publicity to have been erroneous or misleading. This would be a sort of statutory corrective publicity, a simpler, cheap (low-resource), and readily available remedy for the effects of erroneous adverse publicity.

X. Conclusion

Ultimately, the problem of the use of adverse publicity by the FDA boils down to one single issue: how does one balance the need to protect the public's health and safety from potential dangers with the need to protect innocent companies and individuals from potential publicity-induced harm? Considering the pervasive uncertainty that is inherent in attempting to ascertain the potentialities of both these types of dangers, as well as the severe degree of physical and economic harm involved, this question cannot be answered to any one person's satisfaction. Given the FDA's policy and its commitment to its overriding mission of protecting the public, it is unlikely that the FDA will ever give up its use of publicity as a regulatory tool. Perhaps in the future, the agency will once again revive its interest in establishing a publicity policy and propose regulations. One thing is certain. As the trend of increasing governmental activity in protecting the public continues and agencies expand their jurisdictions and duties into new areas, the problem of adverse publicity will become ever more important.

ADVERTISING, THE FDA, AND THE TOBACCO SETTLEMENT:
AS HOPES FOR SETTLEMENT DIM, CHALLENGES OF FDA
AUTHORITY
AND FIRST AMENDMENT CONCERNS ARE REKINDLED

Levi Liu

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Food and Drug Law
Mr. Hutt

February 2, 1998